November 3, 2023

ZOLL Circulation, Inc
Sean Manning
Senior Manager, Regulatory Affairs
2000 Ringwood Avenue
San Jose, California 91531

Re: K231182
Trade/Device Name: Thermogard HQ™ Temperature Management System, Thermogard XP® Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: NZE
Dated: October 12, 2023
Received: October 12, 2023

Dear Sean Manning:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231182

Device Name
Thermogard HQ Temperature Management System
Thermogard XP Temperature Management System

Indications for Use *(Describe)*
Thermogard HQ™ Temperature Management System
Temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients.

Thermogard XP® Temperature Management System
Temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

I. GENERAL INFORMATION

Date Prepared:	October 31, 2023
Submitter:	ZOLL Circulation, Inc.
Address:	2000 Ringwood Avenue San Jose, CA 95131
Phone:	707-696-6666
Fax:	408-541-1030
Contact Person:	Sean Manning, Senior Manager Regulatory Affairs
Secondary Contact:	Nazma Chaudhry, Director Regulatory Affairs

Trade Name:	Thermogard HQ™ Temperature Management System Thermogard XP® Temperature Management System
Common Name:	Thermal Regulating System
Classification/Name:	Class II; System, Thermal Regulating
Regulation:	21 CFR 870.5900, Thermal Regulating System
Product Code:	NZE
Primary Predicate Device:	K100071 EMCOOLSpad
Secondary Predicate Device:	K162523 The IQool™ System

II. DEVICE DESCRIPTION

The subject of this 510(k) is the new surface feature which makes minor modifications to the existing IVTM Start-Up Kits (SUKs) to enable connection of a Thermogard console to the STx™ Vest. The STx™ Vest provides for circulation of thermally conditioned fluid supplied by the Thermogard console (either Thermogard HQ™ or Thermogard XP®). Transfer of heat between the patient and the circulating fluid results in modification of patient core temperature for the purpose of therapeutic patient temperature modulation.

The existing, commercialized Thermogard Systems (Thermogard HQ™ and Thermogard XP®) are used in conjunction with catheters placed in the vasculature to support intravascular cooling. The TGHQ-SURF accessory is a modification of the model TGHQ-500D accessory which was verified, validated, and commercialized. The CG-SURF accessory is a modification of the model CG-500D accessory which was verified, validated, and commercialized. These Surface SUK models are identical to their predecessors with the exception of longer inflow and outflow tubing lengths and replacing the Luers for catheters with 0.25-inch hose barb valved connectors for the STx™ Vest. The Surface SUK also has a label on the fluid spike to indicate the size of bag of fluid (3000ml) to use and to mark it as non-sterile. The Surface SUKs are otherwise identical to their predecessors in terms of materials that contact the heat exchange fluid (i.e., saline), manufacturing process, and packaging materials.

There are no changes to the commercially available Thermogard XP® (K213031) and Thermogard HQ™ (K220008) consoles.

There are no changes to the commercially available STx™ Vest.

III. INDICATIONS FOR USE

Thermogard HQ™ Temperature Management System
Temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients.

Thermogard XP® Temperature Management System
Temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients.

IV. SUBSTANTIAL EQUIVALENCE DISCUSSION

Thermogard Temperature Management System Non-Confidential 510(k) Summary			
Comparison of Subject to Predicate Device:			
Description	**Subject Device**	**Predicate Device**	**Secondary Predicate Device**
Proprietary Name	Thermogard HQ and XP Temperature Management System	EMCOOLSpad	IQool™ System
Common Name	Thermal Regulating System	Thermal Regulating System	Thermal Regulating System
Product Classification Code	NZE	NZE	NZE
Product Regulation Number & Name	21 CFR 870.5900, Thermal Regulating System	21 CFR 870.5900, Thermal Regulating System	21 CFR 870.5900, Thermal Regulating System
Device Class	Class II	Class II	Class II
Device Description	System, Thermal Regulating	System, Thermal Regulating	System, Thermal Regulating
Indications For Use	Temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients.	Temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients.	Temperature reduction in adult patients where clinically indicated, e.g., in hyperthermic patients.
Technical Specifications	Achieves cooling with patient contacting Cooling Pads through which coolant (saline) is circulated. Cooling is controlled by the settings on the device. Consistent temperature reduction is maintained and controlled by the system pushing more or less coolant through the pads as needed achieve or maintain desired cooling.	Achieves cooling through patient contacting Cooling Pads which are filled with a high thermal conductivity material. Pads must be pre-cooled before use. To control cooling, pads are removed from the patient's skin to slow cooling or to stop cooling. The pads are re-applied to the patient's skin to recommence the cooling process.	Achieves cooling with patient contacting Cooling Pads through which coolant is circulated. Cooling is controlled by the settings on the device. Consistent temperature reduction is maintained and controlled by the system pushing more or less coolant through the pads as needed achieve or maintain desired cooling.

The subject device is identical to the predicates in the indications for use. The mechanism of action to achieve the intended use is equivalent between the subject and predicate devices.

V. SUMMARY OF THE NONCLINICAL TESTS PERFORMED

Testing was completed for the Thermogard Temperature Management System used with the Surface Start-Up Kit and STx™ Vest which demonstrated intended, labeled device performance. Performance testing included dimensional verification, functional testing, temperature, flow, pressure, shipping and handling, and standards testing included electrical safety, electromagnetic compatibility, and usability. All testing confirmed that the Thermogard Temperature Management System used with the Surface Start-Up Kit and STx™ Vest operates as described and is substantially equivalent to the predicate devices.

VI. SUMMARY OF THE CLINICAL TESTS PERFORMED

Clinical performance data to demonstrate substantial equivalence was not required.

VII. CONCLUSION

The Thermogard HQ™ Temperature Management System and the Thermogard XP® Temperature Management System used with the Surface Start-Up Kit and STx™ Vest meet the design, performance, and safety specifications when used in accordance with the labeling. It was demonstrated through performance testing, design and features, and non-clinical testing that the proposed devices are substantially equivalent to those of the predicate devices.